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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,001	06/03/2002	Yinghui Dan	38-21(15648)	7199

27161 7590 11/22/2005

MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA)
ST. LOUIS, MO 63167

EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/064,001	Applicant(s) DAN ET AL.	
	Examiner Keith O. Robinson, Ph.D.	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>15 March 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections to Title 35, U.S. Code not included in this action can be found in a prior Office Action, mailed 18 March 2005.

This Office Action is responsive to the amendments filed 22 August 2005.

Claims 2-16 have been amended and no claims have been added or deleted.

Claims 1-16 are examined.

2. The objections to the specification and claims are withdrawn in view of Applicant's amendments (see page 5, second paragraph and third paragraph, respectively, of 'Remarks' filed 22 August 2005).

3. The U.S.C. 112, second paragraph rejection for claims 4, 6 and 13 are withdrawn in view of Applicant's amendments (see page 5, fourth paragraph of 'Remarks' filed 22 August 2005).

Response to Arguments

Claim Rejections - 35 USC § 112, first paragraph

4. Claims 1-16 remain rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement, as stated on pages 2-7 of the last Office Action, mailed 18 March 2005.

Applicant argues that enablement is determined by whether one of skill in the art could make and use the claimed invention without undue experimentation and that this analysis must consider both the teachings in the application and the knowledge available in the art. Applicant further argues that it is not necessary to describe

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information that was already known in the art and that a large quantity of experimentation is permissible, so long as it is routine (see pages 5-8 of the 'Remarks' filed 22 August 2005).

This is not persuasive. The Examiner's rejections were based on scope of enablement (see pages 2-4 of the last Office Action, mailed 18 March 2005) and the lack of guidance, nature of the art, and the unpredictability of the art (see pages 5-7 of the last Office Action, mailed 18 March 2005). The specification fails to provide any evidence or guidance for the use of *Agrobacterium*-mediated transformation and only provides evidence and guidance for the use of particle bombardment (see page 22, paragraph 0085 to page 24, end of paragraph 0091 of the specification). In fact, Applicant states, "the present specification...provide[s] a detailed methodology for particle bombardment" (see page 7, second paragraph of 'Remarks' filed 22 August 2005). Though, particle bombardment and *Agrobacterium*-mediated transformation of wheat is a common place laboratory technique, as stated by Applicant, the success of one does not ensure the success of the other and the specification fails to provide any evidence that *Agrobacterium* would work with the claimed invention. Thus, undue experimentation would be required to determine which, if any, wheat plants could be transformed using the claimed method with *Agrobacterium*. The Examiner, however, agrees with Applicant's assertion that other varieties can be used with the claimed invention using particle bombardment (see page 7, last paragraph of the 'Remarks' filed 22 August 2005).

Applicant argues that the publications cited by the Examiner support the enablement of the present claims (see page 8, first paragraph of the 'Remarks' filed 22 August 2005).

This is not persuasive. Applicant has not provided evidence to refute the evidence provided by the Examiner; therefore the rejections are maintained.

New Claim Rejections - 35 USC § 102(b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fry et al (U.S. Patent 5,631,152, May 20, 1997).

The claim reads on a method of producing a transgenic wheat comprising culturing an explant in a bud inducing media, introducing exogenous DNA, removing buds from first media and transferring said buds to a second media suitable for induction of elongation of buds into shoots, harvesting and transferring said shoots to a culture medium that promotes root development, and culturing said transferred shoots to produce plants.

Fry et al teach a method for producing transgenic wheat comprising culturing explants, introducing exogenous DNA via bombardment, transferring cells from a first media to a second media to induce elongation of buds into shoots, harvesting and

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transferring shoots to a culture medium that promotes root development and culturing transferred shoots to produce plants (see column 7, protocol 1, lines 1-25).

New Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al (Plant Cell Reports 15: 159-163, 1995), in view of Tegeder et al (Plant Cell Reports 15: 164-169, 1995), further in view of Weeks et al (Plant Physiol. 102: 1007-1084, 1993), still further in view of Cheng et al (Plant Physiol. 115: 971-980, 1997).

The claims read on a method of producing a transgenic wheat plant comprising providing an explant presenting a plurality of meristems, culturing said explant in a bud

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inducing media suitable for inducing production of a plurality of buds from at least one of said meristems, introducing exogenous DNA into at least one of said plurality of buds, removing said plurality of buds from said media and transferring said plurality of buds to a second media suitable for induction of elongation of said buds into shoots, harvesting and transferring said shoots to a culture medium that promotes root development, and culturing said transferred shoots to produce plants.

Zhou et al teach a method for producing a transgenic wheat plant comprising an explant, culturing said explant in a bud inducing media, introducing exogenous DNA via particle bombardment, removing buds and transferring to a media suitable for induction of elongation of buds into shoots, harvesting and transferring said shoots to a media that promotes root development, and culturing the transformed shoots to produce plants (see page 160, first column, paragraphs 1-4). Zhou et al also teach the use of picloram as an auxin (see page 160, first column, first paragraph) and selection for plants containing a protein conferring resistance to a selection agent (see page 160, fifth and sixth paragraphs).

Zhou et al do not teach the use of cytokinins, the use of meristems containing the scutellar node, or *Agrobacterium*-mediated transformation.

Tegeder et al teach that cultivation of protocalluses on medium supplemented with the cytokinin thidiazuron resulted in shoot development (see page 164, Abstract).

Weeks et al teach use of scutella for wheat cell culture (see page 1078, first column, second paragraph).

Cheng et al teach the use of *Agrobacterium*-mediated transformation in wheat (see page 972, first column, second paragraph to second column, end of second paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teachings of Zhou et al, Tegeder et al, Weeks et al and Cheng et al to develop a method for producing a transgenic wheat plant.

One of ordinary skill in the art would have been motivated to combine these teachings because Weeks et al teach that wheat is the largest crop in the world in terms of production and that monocotyledonous plants, cereals in particular, have lagged behind dicotyledonous plants in ease and efficiency of transformation (see page 1077, first column, second paragraph to second column, second paragraph).

In addition, one of ordinary skill in the art would have a reasonable expectation of success based on the success of Zhou et al in developing a method for transforming wheat (see page 160, first column, paragraphs 1-7).

New Obvious Type Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 5,631,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of said patent read on a method for producing transformed wheat comprising culturing of plant tissue, introducing exogenous DNA, and culturing shoots to produce plants wherein the steps are similar to those of the instant application.

Conclusion

11. No claims allowed.

12. This is a second non-final because of the new 102, 103, and double patenting rejections that were not issued in the previous Office Action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is

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571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

November 7, 2005

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written over a circular stamp.